

## REMARKS

In the Office Action issued on August 22, 2007, the Examiner:

- acknowledged the filing of a Request for Continued Examination (RCE), withdrew the finality of the previous Office action and entered the submission filed with the Request;
- Indicated that the arguments presented in the submission with respect to Claims 1 through 11 and 13 through 15 are moot in view of new grounds of rejection raised in the action;
- rejected Claims 13 through 15 under 35 U.S.C. §102(e) as being anticipated by McGuckin Jr., et al. (United States Patent No. 6,676,698);
- rejected Claims 13 and 14 under 35 U.S.C. §102(e) as being anticipated by Snyder (United States Patent Application Publication No. 2002/0123802);
- rejected Claims 1 through 3 and 9 through 11 under 35 U.S.C. §102(e) as being anticipated by Shaolian (United States Patent Application Publication No. 2003/0055492);
- rejected Claims 1, 2, 4, 5, 9, 10, 13, and 14 under 35 U.S.C. §102(b) as being anticipated by Baykut (United States Patent No. 4,787,901);
- rejected Claims 4 through 6 under U.S.C. §103(a) as being unpatentably obvious over Shaolian; and
- acknowledged that Claims 7 and 8 define patentable subject matter by objecting to these claims as being dependent upon a rejected base claim and indicating that each claim would be allowable if rewritten in independent form including all limitations of the base and intervening claims.

The Applicants have fully considered the Office Action and cited references and submit this Reply and Amendment in response to the Examiner's rejections.

Reconsideration of the application for patent is requested.

### **Acknowledgement of patentable subject matter – rewriting of Claims 7 and 8**

The Applicants thank the Examiner for acknowledging the patentability of Claims 7 and 8. Each of these claims have been rewritten in independent form to

include all limitations of independent Claim 1, the base claim. These amendments are made solely to present these claims in independent form and do not narrow the scope of the claimed subject matter in any way.

The Examiner's objection to these claims has been fully addressed and should be removed.

### **Rejection of Claims 13 through 15 under 35 U.S.C. §102(e)**

The Examiner rejected Claims 13 through 15 as being anticipated under 35 U.S.C. §102(e) by McGuckin.

The Applicants respectfully traverse this rejection of the claims at least because McGuckin fails to teach a support frame and at least one leaflet that "cooperatively define an opening that permits a controlled amount of fluid flow to pass through said medical device in the second, opposite direction," which is explicitly required by each of Claims 13 through 15.

As clearly illustrated in Figure 41A of McGuckin, the opening 562 is defined completely by the graft member 560. No portion of the support frame defines any portion of the opening. Indeed, a thorough review of McGuckin reveals a complete absence of any such opening. Accordingly, McGuckin fails to teach each and every limitation of any of Claims 13 through 15 and cannot, therefore, properly serve as an anticipatory reference under 35 U.S.C. §102.

This rejection of the claims is improper and should be removed.

### **Rejection of Claims 13 and 14 under 35 U.S.C §102(e)**

The Examiner rejected Claims 13 and 14 as being anticipated under 35 U.S.C. §102(e) by Snyders.

The Applicants respectfully traverse this rejection of the claims at least because Snyders fails to teach a support frame and at least one leaflet that "cooperatively define an opening that permits a controlled amount of fluid flow to pass through said medical device in the second, opposite direction," which is explicitly required by each of Claims 13 and 14.

As clearly illustrated in Figure 15 and described in paragraph [0058], the opening 212 referenced by the Examiner is completely defined by post 310, which is a separate member attached to the support frame. *No portion of the support frame nor of the leaflet defines any portion of the opening.* Indeed, a thorough review of Snyders reveals a complete absence of any such opening. Accordingly, Snyders fails to teach each and every limitation of Claim 13 and Claim 14 and cannot, therefore, properly serve as an anticipatory reference under 35 U.S.C.

§102.

This rejection of the claims is improper and should be removed.

**Rejection of Claims 1 through 3 and 9 through 11 under 35 U.S.C. §102(e)**

The Examiner rejected Claims 1 through 3 and 9 through 11 under 35 U.S.C. §102(e) as being anticipated by Shaolian.

Applicants respectfully direct the Examiner's attention to the amendment made to independent Claim 1 herein. As amended, Claim 1 requires that the "opening that permits a controlled amount of fluid flow to pass through said medical device" to have "*a substantially fixed size.*"

This amendment to Claim 1 is fully supported by the specification as filed; no new matter has been introduced. Exemplary support is found in Figures 5, 8, and 9, and the accompanying descriptions.

Both the valve orifice and the opening of the device taught by Shaolian, as interpreted by the Examiner, have variable sizes. The device operates via a pivoting movement of the leaflet within the support frame, which continually alters the size of both the valve orifice and the opening (as interpreted by the Examiner).

Claim 1, as amended herein, requires that the opening have "a substantially fixed size." A thorough review of Shaolian reveals a complete lack of a teaching or suggestion of such an opening. Accordingly, Shaolian fails to teach each and every limitation of amended Claim 1 and cannot properly serve as an anticipatory reference for any of Claims 1 through 3 and 9 through 11.

The Applicants respectfully request that this rejection of the claims has been overcome and request reconsideration of the claims.

**Rejection of Claims 1, 2, 4, 5, 9, 10, 13, and 14 under 35 U.S.C. §102(b)**

The Examiner rejected Claims 1, 2, 4, 5, 9, 10, 13, and 14 as being anticipated under 35 U.S.C. §102(b) by Baykut.

The Applicants respectfully traverse this rejection of the claims at least because Baykut fails to teach "an opening that permits a controlled amount of fluid flow to pass through said medical device in the second, opposite direction," which is explicitly required by each of the rejected claims.

The Examiner states that "a portion of the frame (3) and second edge (bottom edge of 2) form an opening (seen in figs. 9, 10 below stitching of 2 to

vessel)....”

The Applicants respectfully assert that, even if Baykut teaches an opening as described by the Examiner, the opening fails to permit “a controlled amount of fluid flow to pass *through said medical device* in the second, opposite direction.” As clearly illustrated in Figure 10, the opening, as characterized by the Examiner, opens to a dead space in the vessel that has no escape pathway that would allow fluid flow to pass *through said medical device*. Rather, the fluid that enters the opening would be trapped in the dead space *contained within the medical device*.

A thorough review of Baykut reveals a complete absence of any teaching that meets the limitation described above. Accordingly, Baykut fails to teach each and every limitation of any of Claims 1, 2, 4, 5, 9, 10, 13, and 14 and cannot, therefore, properly serve as an anticipatory reference for any of these claims under 35 U.S.C. §102.

This rejection of the claims is improper and should be removed.

#### **Rejection of Claims 4 through 6 under 35 U.S.C. §103(a).**

The Examiner rejected Claims 4 through 6 under 35 U.S.C. §103(a) as being unpatentably obvious over Shaolian.

Each of Claims 4 through 6 depends from independent Claim 1, which has been amended herein. As detailed above, Shaolian fails to teach each and every limitation of Claim 1 and, therefore, fails to teach each and every limitation of any of Claims 4 through 6. Accordingly, Shaolian, without more, cannot properly serve as the basis for an obviousness rejection of these claims.

The Applicants respectfully request that this rejection of the claims has been overcome and request reconsideration of the claims.

## **CONCLUSION**

The Applicants have fully responded to the objections and rejections listed by the Examiner in the August 22, 2007 Office action. Applicants respectfully assert that all pending claims define patentable subject matter and request their reconsideration and issuance of an appropriate Notice of Allowability.

Should the Examiner have any questions regarding this Reply and Amendment, or the remarks contained herein, the undersigned attorney would welcome the opportunity to discuss such matters with the Examiner.

Respectfully submitted,

/J. Matthew BUCHANAN, Reg. No. 47459/

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J. Matthew Buchanan  
Reg. No. 47,459  
DUNLAP, CODDING and ROGERS, P.C.  
Customer No. 42715  
P.O. Box 16370  
Oklahoma City, Oklahoma 73113  
Telephone: (405) 607-8600  
Facsimile: (405) 607-8686  
E-Mail: matt\_buchanan@okpatents.com  
Web Site: www.okpatents.com

Attorney for Applicants